IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:19-CV-505-D

AQUESTIVE THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**ORDER**
	)	
BIODELIVERY SCIENCES INTERNATIONAL, INC.,	)	
	)	
	)	
Defendant.	)	

On May 7, 2020, Aquestive Therapeutics, Inc. ("Aquestive" or "plaintiff") moved to dismiss Biodelivery Sciences International, Inc.'s ("BDSI" or "defendant") Third Counterclaim and to strike BDSI's Fourth and Sixth Affirmative Defenses [D.E. 29], and filed a memorandum in support [D.E. 30]. On May 28, 2020 BDSI amended its answer [D.E. 31], and responded in opposition [D.E. 32]. On June 11, 2020, Aquestive replied [D.E. 34].[1] On June 25, 2020, Aquestive moved to dismiss BDSI's Amended Third Counterclaim and renewed its motion to strike BDSI's Fourth and Sixth Affirmative Defenses [D.E. 35], and filed a memorandum in support [D.E. 36]. On July 16, 2020, BDSI responded in opposition [D.E. 38]. On July 30, 2020, Aquestive replied [D.E. 39]. As explained below, the court dismisses as moot Aquestive's motion to dismiss BDSI's Third

[1] In its response, BDSI argues that its amended answer moots Aquestive's motion to dismiss. See [D.E. 32] 2–3. In its reply, Aquestive acknowledges that BDSI's amended answer renders its original motion to dismiss moot. See [D.E. 34] 2. Both parties are correct. See Young v. City of Mount Ranier, 238 F.3d 567, 572 (4th Cir. 2001); Save Our Sound OBX, Inc. v. N.C. Dep't of Transp., No. 2:17-CV-4-FL, 2017 WL 3908093, at *1 n.2 (E.D.N.C. Sept. 5, 2017) (unpublished). Thus, the court dismisses as moot Aquestive's original motion to dismiss [D.E. 29].

Counterclaim, grants in part and denies in part Aquestive's motion to dismiss BDSI's Amended Third Counterclaim, and denies Aquestive's motion to strike.

I.

BDSI is a pharmaceutical company with its principal place of business in North Carolina that engages in research and development "geared towards bringing new pharmaceutical products to market in the United States and the rest of the world, including products for the treatment of severe pain." [D.E. 31] 14. BDSI's products include pharmaceutical films, products designed to deliver drugs orally through strips that dissolve on contact with the buccal cavity. See id. at 15. Aquestive also develops, markets, and sells pharmaceutical products, including pharmaceutical films. See id. at 14. Aquestive is a Delaware corporation with its principal place of business in Warren, New Jersey. See id. Pharmaceutical films have numerous advantages over other drug delivery mechanisms, such as tablets and pills. See id. at 5; Compl. [D.E. 1] ¶ 13.

Over the past decade, BDSI and Aquestive have sparred in multiple patent infringement cases. See [D.E. 31] 15. BDSI and Aquestive's most recent legal battle centers on alleged infringement of United States Patent No. 8,765,167 (the "'167 patent"). See Compl. [D.E. 1]. The '167 patent is assigned to Aquestive and relates to "water-soluble films incorporating anti-tacking agents and methods of their preparation." [D.E. 31] 5; see Compl. [D.E. 1] ¶ 13. Garry Myers ("Myers") is the first named inventor of the '167 patent and was an Aquestive employee from 2002 to 2015. See [D.E. 31] 26. Daniel Scola, Jr. ("Scola") and Michael Chakansky ("Chakansky") are attorneys with Hoffman & Barron, LLP ("Hoffman"), and prosecuted the '167 patent, its parent patent, and other patents of the same family on behalf of Aquestive. See id. Myers, Scola, and Chakansky were involved in the prosecution and inter partes reviews of the '167 patent. See id. In

particular, Aquestive "directed that all correspondence in the '167 patent application be directed to Mr. Scola." Id.

While prosecuting the '167 patent at the United States Patent and Trademark Office (the "Patent Office"), Aquestive had issues with prior art. Specifically, the Patent Office initially rejected the '167 patent over a prior art reference called Staab. See id. at 28. After this initial rejection, Scola spoke with patent examiners and proposed amending the '167 patent to add new limitations to overcome the Staab prior art reference. See id. On August 10, 2010, attorneys at Hoffman amended the '167 patent application, adding language to the effect that the '167 patent's "active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." Id. at 27–28 (emphasis omitted). The inventors did not include this language in the '167 patent claims as originally filed. See id. at 28. Nevertheless, the Patent Office rejected the '167 patent as obvious in light of Staab, which teaches that "the agent material is evenly distributed throughout the film." Id. at 29.

On May 2, 2012, Aquestive and Hoffman again amended the '167 patent, including language in claim 1 reciting "a substantially uniform distribution of an active component [wherein] said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by . . . more than 10%." Id. at 30 (emphasis omitted). Aquestive argued that this language distinguished the '167 patent from Staab because "Staab fails to disclose or suggest that the visco-elastic film must be formed having no more than 10% variance." Id. Myers and Scola reinforced the importance of the 10% limitation, alleging that "[c]urrently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present." Id. at 31.

Myers and Scola's allegation regarding regulatory requirements conflicted with Myers and Aquestive's other statements to the Patent Office. See id. For example, while prosecuting United States Patent No. 8,663,687 (the "'687 patent"), Myers stated that "[c]urrently, as generally required by various world regulatory authorities, dosage forms may not vary more than 10–15% in the amount of active present." Id. Additionally, six days after Myers's representations to the Patent Office regarding the 10% limitation, another Aquestive expert, Dr. Robert Langer ("Dr. Langer"), testified in a separate case involving a patent claiming the same priority as the '167 patent. See id. at 32 n.1. In that case, Dr. Langer testified that "the FDA has a variation of 15 percent, not 10 percent." Id.

Following the May 2, 2012 amendment, the Patent Office, apparently unaware of these inconsistencies, allowed several of the '167 patent's claims based on the 10% limitation stating that the examiner "notes the term 'substantially uniform' for the distribution of active also has to meet the less than 10% variance in the matrix limitation, and therefore is not indefinite." Id. at 30 (emphasis omitted). On July 1, 2014, the Patent Office issued the '167 patent. See id. at 31; [D.E. 1] ¶ 12.

In late 2014, BDSI challenged the validity of the '167 patent through the Patent Office's inter partes review process. See [D.E. 31] 16. During inter partes review, Myers, Scola, and Chakansky continued to make representations regarding the alleged 10% regulatory requirement. See id. at 32. For example, Scola stated that "individual unit doses . . . vary no more than +/- 10% from the labeled dosage amount . . . and thus comply with the FDA uniformity requirements." [D.E. 31-1] 3. Additionally, in response to BDSI's challenges during the inter partes review, Scola and Chakansky filed a patent owner response that included expert declarations from Dr. Joseph Wyse ("Dr. Wyse") and Dr. Nicholas Peppas ("Dr. Peppas"). See [D.E. 31] at 33. This patent owner response stated that "using microscopy, Dr. Wyse examined Chen Example 8 films of Estradiol individual unit doses

prepared in accordance with Chen. His examination of photomicrographs taken of the films visually confirmed the lack of uniformity in the distribution of Chen's Example 8 film components, including Estradiol, and the presence of agglomerated/aggregated particles." Id. (emphasis omitted). Scola and Chakansky also told the Patent Office that "Dr. Peppas was provided by Hoffman & Baron with several photomicrographs that Dr. Wyse took of films he made of Example 8 of Chen," and Dr. Peppas used these photomicrographs in producing his declaration in favor of patentability. Id. at 34. Aquestive and Hoffman used Dr. Wyse and Dr. Peppas's declarations to advance their patentability arguments, claiming that the '167 patent overcame problems with agglomerations/aggregations which caused films produced in accordance with prior art to be "insufficiently uniform." Id. at 38. On cross examination, Dr. Wyse admitted that he had failed to take photomicrographs of films produced in accordance with prior art and that the nonuniformity resulted from "improper casting" techniques. See id. at 35–38. Accordingly, BDSI moved, inter alia, to exclude Dr. Wyse and Dr. Peppas's declarations. See [D.E. 37-1] 29. Despite BDSI's challenges, the Patent Office's Final Written Decision found that the '167 patent's claims "have not been shown by a preponderance of the evidence to be unpatentable." Id. at 31. Moreover, the Patent Office denied as moot BDSI's motion to exclude Dr. Wyse's and Dr. Peppas's declarations, stating that its final decision "does not rely on those declarations." Id. at 29–30.

After the Patent Office approved the '167 patent, BDSI submitted a New Drug Application under 21 U.S.C. § 355(b)(2) to the Food and Drug Administration ("FDA") seeking approval to market a new pharmaceutical product: individual unit doses of buprenorphine buccal film under the trademark BELBUCA. See Compl. [D.E. 1] ¶ 3; [D.E. 31] 15. On October 25, 2015, the FDA approved BDSI's application. See [D.E. 31] 15. Thereafter, BDSI began marketing and selling BELBUCA as a product for the management of severe pain that would ordinarily require "daily,

around-the-clock, long-term opioid treatment" and for which "alternative treatment options are inadequate." Id.

On November 11, 2019, Aquestive filed this action against BDSI alleging infringement of the '167 patent. See Compl. [D.E. 1]. Aquestive alleges, inter alia, that although BDSI knew of the '167 patent, BDSI nonetheless sought FDA approval of and marketed BELBUCA, a product that infringes on the '167 patent. See id. ¶¶ 3–5. On April 16, 2020, BDSI answered by denying Aquestive's infringement allegations and asserting three counterclaims and eleven affirmative defenses. See [D.E. 27].

II.

In patent cases, the application of Rules 12(b)(6) and 12(f) of the Federal Rules of Civil Procedure is a procedural question governed by the law of the regional circuits. See Monsanto Co. v. E.I. Du Pont de Nemours & Co., 748 F.3d 1189, 1196 (Fed. Cir. 2014); McZeal v. Sprint Nextel Corp., 501 F.3d 1354, 1355–56 (Fed. Cir. 2007). A motion to dismiss under Rule 12(b)(6) tests the complaint's legal and factual sufficiency. See Ashcroft v. Iqbal, 556 U.S. 662, 677–80 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 554–63 (2007); Coleman v. Md. Court of Appeals, 626 F.3d 187, 190 (4th Cir. 2010), aff'd, 566 U.S. 30 (2012); Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008). To withstand a Rule 12(b)(6) motion, a pleading "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 678 (quotation omitted); see Twombly, 550 U.S. at 570; Giarratano, 521 F.3d at 302. In considering the motion, the court must construe the facts and reasonable inferences "in the light most favorable to [the nonmoving party]." Massey v. Ojaniit, 759 F.3d 343, 352 (4th Cir. 2014) (quotation omitted); see Clatterbuck v. City of Charlottesville, 708 F.3d 549, 557 (4th Cir. 2013), abrogated on other grounds by Reed v. Town of Gilbert, 576 U.S. 155 (2015). A court need not accept as true a

complaint's legal conclusions, "unwarranted inferences, unreasonable conclusions, or arguments." Giarratano, 521 F.3d at 302 (quotation omitted); see Iqbal, 556 U.S. at 678–79. Rather, a plaintiff's factual allegations must "nudge[ ] [its] claims," Twombly, 550 U.S. at 570, beyond the realm of "mere possibility" into "plausibility." Iqbal, 556 U.S. at 678–79.

When evaluating a motion to dismiss, a court considers the pleadings and any materials "attached or incorporated into the complaint." E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see Fed. R. Civ. P. 10(c); Goines v. Valley Cmty. Servs. Bd., 822 F.3d 159, 165–66 (4th Cir. 2016); Thompson v. Greene, 427 F.3d 263, 268 (4th Cir. 2005). A court also may consider a document submitted by a moving party if it is "integral to the complaint and there is no dispute about the document's authenticity." Goines, 822 F.3d at 166. Additionally, a court may take judicial notice of public records without converting the motion to dismiss into a motion for summary judgment. See, e.g., Fed. R. Evid. 201; Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 322 (2007); Philips v. Pitt Cnty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009).

Under Federal Rule of Civil Procedure 12(f), "[a] court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "A defense is insufficient if it is clearly invalid as a matter of law." Racick v. Dominion Law Assocs., 270 F.R.D. 228, 232 (E.D.N.C. 2010) (quotation omitted); see Spell v. McDaniel, 591 F. Supp. 1090, 1112 (E.D.N.C. 1984). An insufficient defense "can and should be deleted." Waste Mgmt. Holdings, Inc. v. Gilmore, 252 F.3d 316, 347 (4th Cir. 2001) (quotation omitted); 5C Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1381 (3d ed. 2020). Although many courts view granting a motion to strike as a "drastic remedy," the court retains the discretion to do so. See Waste Mgmt., 252 F.3d at 347; Massenburg v. Innovative Talent Sols., Inc., No. 5:16-

CV-957-D, 2019 WL 441172, at *11 (E.D.N.C.), aff'd, 779 F. App'x 174 (4th Cir. 2019) (per curiam) (unpublished); Reale v. Wake Cnty. Hum. Servs., No. 5:11-CV-682-D, 2013 WL 2635181, at *6 (E.D.N.C. June 12, 2013) (unpublished).

III.

Aquestive moves to dismiss BDSI's Amended Third Counterclaim and argues that BDSI failed to adequately plead inequitable conduct, and moves to strike BDSI's Fourth and Sixth Affirmative Defenses for the same reason. "[W]hether inequitable conduct has been adequately pleaded is a question of Federal Circuit law because it 'pertains to or is unique to patent law.'" Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326 (Fed. Cir. 2009) (citation omitted); see W.L. Gore & Assocs., Inc. v. Medtronic, Inc., 850 F. Supp. 2d 630, 633 (E.D. Va. 2012). "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." Therasense, Inc. v. Becton, Dickinson, & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011); see Regeneron Pharms., Inc. v. Merus N.V., 864 F.3d 1343, 1350 (Fed. Cir. 2017).

"The substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO." Exergen, 575 F.3d at 1327 n.3 (collecting cases); see Rothman v. Target Corp., 556 F.3d 1310, 1323 (Fed. Cir. 2009); Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363 (Fed. Cir. 2007). "Intent and materiality are separate requirements." Therasense, 649 F.3d at 1290. "A district court may not infer intent solely from materiality," but must instead "weigh the evidence of intent to deceive independent of its analysis of materiality." Id.

Generally, "the materiality required to establish inequitable conduct is but-for materiality." Id. at 1291; see Regeneron, 864 F.3d at 1350. "Information is material if a reasonable examiner would have considered it important to the patentability of a claim." Exergen, 575 F.3d at 1329; see Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1570 (Fed. Cir. 1997). In assessing materiality, "the court must determine whether the PTO would have allowed the claim if it had been aware" of the material misrepresentation or omission. Therasense, 649 F.3d at 1291; see Rothman, 556 F.3d at 1323; Symantec Corp. v. Comput. Assocs. Int'l, Inc., 522 F.3d 1279, 1297 (Fed. Cir. 2008). However, where "a patentee has engaged in affirmative acts of egregious conduct, such as the filing of an unmistakably false affidavit, the misconduct is material," and these "extraordinary circumstances" obviate the need to allege but-for materiality. Therasense, 649 F.3d at 1292–93.

The intent required to establish inequitable conduct is "knowledge of the withheld information or of the falsity of the material misrepresentation" and a "specific intent to deceive the PTO." Exergen 575 F.3d at 1327; see Rothman, 556 F.3d at 1323. "[P]laintiffs must allege facts that give rise to a strong inference of fraudulent intent." Exergen, 575 F.3d at 1327 n.4 (quotation omitted); see Lerner v. Fleet Bank, N.A., 459 F.3d 273, 290 (2d Cir. 2006). Specifically, a pleading must "plausibly suggest [a] deliberate decision to withhold a known material reference or to make a knowingly false misrepresentation." Exergen, 575 F.3d at 1331 (citation and quotations omitted). "[A] district court may infer intent from indirect and circumstantial evidence." Therasense, 649 F.3d at 1290. However, an allegation that an actor "should have known" the materiality of undisclosed information is insufficient to allege inequitable conduct. Id. at 1296. Likewise, allegations of "gross negligence alone [are] not enough to justify an inference of intent to deceive." Id. at 1291; Rothman, 556 F.3d at 1323. Furthermore, "[t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive." Therasense, 649 F.3d at 1291.

A defendant alleging inequitable conduct must satisfy Federal Rule of Civil Procedure 9(b)'s pleading requirements. See Exergen, 575 F.3d at 1327; Andritz Inc. v. Cortex N. Am. Corp., No. 3:20-cv-00029-SB, 2020 WL 4495267, at *1 (D. Or. Aug. 4, 2020) (unpublished); CertusView Techs., LLC v. S & N Locating Servs., LLC, 107 F. Supp. 3d 500, 505 (E.D. Va. 2015); Wright Asphalt Prods. Co. v. Pelican Refin. Co., No. H-09-1145, 2011 WL 2037631, at *5 (S.D. Tex. May 20, 2011) (unpublished). Rule 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

To satisfy Rule 9(b), an inequitable conduct pleading "must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." Exergen, 575 F.3d at 1327–29; Sanders v. The Mosaic Co., 418 F. App'x 914, 918 (Fed. Cir. 2011) (unpublished).[2] Additionally, "[a]lthough 'knowledge' and 'intent' may be averred generally," a pleading must include sufficient allegations of underlying facts from which "a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Exergen, 675 F.3d at 1327–29. Although an inference of specific intent "must be the single most reasonable inference able to be drawn from the evidence" to prevail on the merits, id. at 1329 n.5 (quotation and emphasis omitted), "[a]t the pleading stage the proponent of the inequitable conduct theory need only plead facts supporting a reasonable inference that a specific

[2] "[T]he goals of Rule 9(b), . . . include the deterrence of frivolous litigation based on accusations that could hurt the reputations of those being attacked." Exergen, 575 F.3d at 1331 (quotation omitted). Rule 9(b)'s particularity requirements help to prevent inequitable conduct from devolving into a "magic incantation to be asserted against every patentee and its allegation [from being] established upon a mere showing that art or information having some degree of materiality was not disclosed." Id. (quotations omitted).

individual knew of the misrepresentation and had the specific intent to deceive the PTO." Sanders, 418 F. App'x at 919. "A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b)." Exergen, 575 F.3d at 1326–27.

Under Rule 12(b)(6), a court may dismiss a counterclaim that fails to satisfy Rule 9(b)'s particularity requirements. Medtronic, 850 F. Supp. 2d at 633; Wright, 2011 WL 2037631 at *5–6. Likewise, under Rule 12(f) a court may strike an affirmative defense that fails to satisfy Rule 9(b)'s particularity requirements. See Waste Mgmt., 252 F.3d at 347; Andritz, 2020 WL 4495267, at *6.

BDSI's Amended Third Counterclaim alleges that the '167 patent is unenforceable because of inequitable conduct. See [D.E. 31] 25. BDSI bases its counterclaim on (1) intentional misrepresentations regarding "Uniformity Requirements" and (2) intentional misrepresentations and omissions regarding films and photomicrographs. See id. at 27–41. Aquestive moves to dismiss BDSI's Amended Third Counterclaim and argues that BDSI has not adequately pleaded (1) the who, what, and how of the alleged material misrepresentations or omissions and (2) facts from which an intent to deceive plausibly can be derived. See [D.E. 36] 7–10. BDSI responds that it has pleaded facts that "exceed[] the heightened standard for pleading inequitable conduct." [D.E. 38] 2.

A.

In BDSI's inequitable conduct counterclaim, BDSI alleges that Aquestive intentionally misrepresented regulatory "Uniformity Requirements" to the Patent Office. See [D.E. 31] 27–33. Specifically, BDSI alleges that Myers and Scola "knowingly misrepresented federal regulatory requirements for drug uniformity in pharmaceutical film dosage forms with the intent to deceive the PTO." Id. at 27. Aquestive moves to dismiss this counterclaim and makes several arguments concerning how BDSI's allegations fail to adequately plead inequitable conduct.

First, Aquestive argues that the alleged "Uniformity Requirements" misrepresentations were made in the context of "attorney arguments" and therefore cannot be grounds for an inequitable conduct claim. See [D.E. 36] 14. As a general rule, "a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." Rothman, 556 F.3d at 1328–29. Thus, courts repeatedly have held that "legitimate attorney argument[s]" are not grounds for inequitable conduct counterclaims. See id.; Illumina, Inc. v. BGI Genomics Co., No. 19-cv-03770-WHO, 2020 WL 571030, at *2–3 (N.D. Cal. Feb. 5, 2020) (unpublished); Wright, 2011 WL 2037631, at *1. However, this safe harbor generally applies only to attorney arguments that "proposed inventions [are] distinguishable from . . . disclosed prior art patents." Wright, 2011 WL 2037631, at *1; see Rothman, 556 F.3d at 1329; Illumina, 2020 WL 571030, at *2. Moreover, although lawyers are "free to present arguments about why an invention may be patented over disclosed prior art," their arguments are not insulated from inequitable conduct claims where their arguments include "demonstrably false" statements. Wright, 2011 WL 2037631, at *1, 8; see Young v. Lumenis, Inc., 492 F.3d 1336, 1349 (Fed. Cir. 2007). Additionally, where a party "constructively with[holds]" prior art, such as by mischaracterizing and partially translating a foreign document, that conduct may amount to "genuine misrepresentations of a material fact regarding a prior art reference and may support an inequitable conduct claim." Illumina, 2020 WL 571030, at *2; see Semiconductor Energy Lab'y Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1377 (Fed. Cir. 2000).

Accepting BDSI's allegations as true, Rothman's safe harbor does not protect the alleged misrepresentations.[3] Scola argued in favor of patentability that the '167 patent complied with

[3] Notably, BDSI's allegations regarding Myers's alleged misrepresentations to the Patent Office are not "attorney arguments" because Myers is the first named inventor, not an attorney. See [D.E. 31] 26. Thus, Rothman's safe harbor also does not shelter Myers's alleged misrepresentations.

regulatory requirements. See [D.E. 31] 27–33. Specifically, Scola told the Patent Office that prior art "would not likely meet the stringent standards of governmental or regulatory agencies, such as the [FDA], relating to the variation of active in dosage forms. Currently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present." [D.E. 1-1] 12. Scola also amended '167's claims and filed a patent owner response, adding language arguing compliance with a 10% limitation to overcome prior art reference. See [D.E. 31] 28. Additionally, during inter partes review, Scola argued that "individual unit doses . . . vary no more than +/- 10% from the labeled dosage amount . . . and thus comply with the FDA uniformity requirements." [D.E. 31-1] 3. BDSI alleges that because "the FDA has no standard 10% requirement for drug uniformity," Scola made demonstrably false statements to the Patent Board. [D.E. 31] 32–33. BDSI cites no FDA regulations to support their claim, but references the testimony of one of Aquestive's experts, Dr. Robert Langer, as evidence that "the FDA has a variation of 15 percent, not 10 percent." Id. at 32 n.1 (emphasis omitted).

BDSI has plausibly alleged that Scola's misrepresentations are demonstrably false. Specifically, BDSI has plausibly alleged that Scola's statement in the '167 patent that "dosage forms may not vary more than 10% in the amount of active present," is false in light of Aquestive's expert testimony that "the FDA has a variation of 15 percent, not 10 percent." Id. Moreover, unlike the attorney arguments in Rothman, Illumina, and Wright, which turned on the attorneys' characterizations of prior art, Scola's alleged statements centered on alleged federal regulatory requirements. Thus, BDSI has plausibly alleged that Scola's statements are not "legitimate attorney argument" and may serve as grounds for BDSI's inequitable conduct claim. See Rothman 556 F.3d at 1328–29; Young, 492 F.3d at 1349; Samsung, 204 F.3d at 1377; Illumina, 2020 WL 571030, at *2–3; Wright, 2011 WL 2037631, at *1, 8.

Next, Aquestive argues that BDSI failed to adequately plead materiality. To plead materiality, a party must allege that "an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact." Exergen, 575 F.3d at 1327 n.3. "Information is material if a reasonable examiner would have considered it important to the patentability of a claim." Id. at 1329 (quotation and emphasis omitted); see Eli Lilly, 119 F.3d at 1570. The counterclaim also must "identify the specific who, what, when, where, and how of the material misrepresentation," Exergen, 575 F.3d at 1327–29, and establish that "but-for" the misrepresentations, the Patent Office would not have allowed the patent. Therasense, 649 F.3d at 1291.

To adequately allege the "who" element, the counterclaim must "name the specific individual associated with the filing or prosecution of the [patent application], who both knew of the material information and deliberately withheld or misrepresented it." Exergen, 575 F.3d at 1329. To allege the "what" element, the counterclaim must identify "which claims, and which limitations in those claims, the [misrepresentations] are relevant to." Id. To allege the "how" element, the counterclaim must identify the misrepresentation and explain how "an examiner would have used this information in assessing the patentability of the claims." Id. at 1330. Failure to allege the who, what, or how is "fatal under Rule 9(b)." Id.

BDSI has adequately pleaded the "who," "what," and "how" elements.[4] First, BDSI alleged

[4] BDSI also has adequately pleaded the "when" and "where" elements. The "when" element refers to when the misrepresentation was made. Exergen, 575 F.3d at 1330–31. The "where" element refers to "where in the [misrepresentations] the material information is found." Id. at 1329. As for the when element, BDSI alleges the misrepresentations were made both during '167 patent prosecution and during inter partes review. See [D.E. 31] 27–33. As for the where element, BDSI identifies the various patent claims, amendments, and depositions where Aquestive allegedly made the material misrepresentations regarding federal regulatory uniformity requirements. See id.

that both Scola and Myers knew the federal regulatory requirements and deliberately misrepresented them to the Patent Office. See [D.E. 31] 27. These allegations are sufficient to plead the "who" element. See Exergen, 575 F.3d at 1329. Second, BDSI alleged that the misrepresented uniformity requirements are relevant to the '167 patent's "'10%' limitation [which was added] to overcome the Staab prior art reference." Id. at 28–33. Thus, BDSI adequately pleaded the "what" element. See Exergen, 575 F.3d at 1329. Finally, BDSI alleged that the Patent Office issued the '167 patent over the Staab prior art considerations only after Scola and Myers made the "misrepresentations concerning the '10%' limitation." [D.E. 31] 29–31, 33. These allegations are sufficient to plead the "how" element. See Exergen, 575 F.3d at 1330. Accordingly, BDSI has adequately pleaded materiality. See Sanders, 418 F. App'x at 918; Exergen, 575 F.3d at 1328–29.

Next, Aquestive argues that BDSI failed to adequately plead specific intent. To plead specific intent, a party must sufficiently allege underlying facts from which "a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Exergen, 675 F.3d at 1328–29. "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." Therasense, 649 F.3d at 1290. "At the pleading stage the proponent of the inequitable conduct theory need only plead facts supporting a reasonable inference that a specific individual knew of the misrepresentation and had the specific intent to deceive the PTO." Sanders, 418 F. App'x at 919.

BDSI has pleaded sufficient facts for the court to reasonably infer the specific intent necessary to support its inequitable conduct counterclaim. Specifically, BDSI alleges that Scola "was responsible for the prosecuting of the '167 patent," that the patent's application was filed at "Scola's direction," and that "Scola was responsible for the amendment" containing the material

misrepresentations that resulted in the Patent Office allowing the '167 patent. [D.E. 31] 27–28. BDSI also alleges that Scola was responsible for prosecuting "other patents in the same family [as the '167 patent] on behalf of Aquestive." Id. at 26. As for Myers, BDSI alleges that he "is the first named inventor on the '167 patent" and that Myers was an inventor of the '687 patent. Id. at 26, 31.

BDSI asserts that both Scola and Meyer knew that the 10% uniformity requirement was a misrepresentation based on statements Aquestive made prosecuting other Aquestive patents. Specifically, BDSI cites Aquestive's representation in the application for the '687 patent that "[c]urrently, as generally required by various world regulatory authorities, dosage forms may not vary more than 10-15% in the amount of active present." Id. at 31 (emphasis omitted). BDSI also cites testimony by one of Aquestive's experts, Dr. Langer, made in the prosecution of another patent in the '167 family and concurrent with the prosecution of the '167 patent. Id. at 32 n.1. There, Dr. Langer asserted that "the FDA has a variation of 15 percent, not 10 percent." Id. (emphasis omitted).

Although the evidence is circumstantial, BDSI's allegations of Myers and Scola's involvement with multiple Aquestive patent prosecutions in the '167 family allow the court at this stage of the litigation to reasonably infer that they both knew that federal regulations provided for a 10-15% variation and that their representation to the Patent Office of a 10% limitation was false. Additionally, given the necessity of overcoming the Staab prior art, the court at this stage of the litigation also may reasonably infer that Myers and Scola's misrepresentations regarding uniformity requirements were made with a specific intent to deceive the Patent Office. See Therasense, 649 F.3d at 1290. Whether this inference is the "single most reasonable inference that can be drawn from the evidence" is an issue for another day. At this stage of the litigation, the court only need find that BDSI's facts support "a reasonable inference" that Myers and Scola "knew of the misrepresentation and had the specific intent to deceive the PTO." Sanders, 418 F. App'x at 919 (emphasis added).

It does. Thus, the court denies Aquestive's motion to dismiss insofar as it rests on BDSI's allegations regarding uniformity requirements.

B.

BDSI also contends in its inequitable conduct counterclaim that Aquestive made intentional misrepresentations or omissions to the Patent Office regarding films and micrographs. See [D.E. 31] 33–41. Specifically, BDSI alleges that Chakansky and Scola "knowingly withheld material information and made material misrepresentations regarding film made by [Wyse] with knowledge of the withheld material information and the falsity of the material misrepresentations," that they "did so with specific intent to deceive the PTO," and, as a result, numerous claims "survived inter partes reviews." Id. at 33, 41. Aquestive also moves to dismiss this aspect of the counterclaim and argues that (1) Chakansky and Scola's statements were attorney arguments and "cannot form the basis for an inequitable conduct claim," (2) BDSI fails to adequately plead materiality where the Patent Office's decision did not rely on the alleged misrepresentations or omissions, and (3) BDSI "fail[s] to allege plausibly that a specific intent to deceive is the 'single most reasonable inference that can be drawn from the evidence.'" [D.E. 36] at 18–21.

The court need not address Aquestive's first and third arguments because the alleged misrepresentations and omissions are not material. "Information is material if a reasonable examiner would have considered it important to the patentability of a claim." Exergen, 575 F.3d at 1329 (quotation omitted). Where an inequitable conduct counterclaim fails to adequately allege materiality, it fails. See id. at 1327 n.3; Rothman, 556 F.3d at 1323. BDSI bases this part of its counterclaim on Chakansky and Scola's alleged misrepresentation of a declaration by Wyse. See [D.E. 31] 33. However, in its Final Written Decision, the Patent Office stated that its decision to allow the '167 patent "does not rely on [Wyse's] declaration[]." [D.E. 37-1] 29–30. Because the

Patent Office's statement demonstrates that it did not consider the Wyse declaration "important to the patentability of [the '167] claim," the alleged misrepresentations are not material. Exergen, 575 F.3d at 1329. Thus, the court dismisses this aspect of BDSI's Amended Third Counterclaim.

C.

BDSI alleges eleven affirmative defenses to Aquestive's infringement claim. BDSI's Fourth Affirmative Defense alleges that the "'167 patent is invalid and unenforceable for failure to comply with one or more of the requirements of 35 U.S.C. § 101 et seq., including, without limitation, sections 101, 102, 103 and/or 112." [D.E. 31] 12. BDSI's Sixth Affirmative Defense alleges that "Aquestive's claims are barred by the equitable doctrines of waiver, estoppel, laches, and unclean hands." Id. at 13. Aquestive moves to strike both affirmative defenses claiming that they "are inadequately plead[ed] for the same reasons as BDSI's Third Counterclaim is inadequately plead[ed]." [D.E. 39] 11. As for BDSI's Fourth Affirmative Defense, Aquestive argues that it "relates to the unenforceability theory of BDSI's Third Counterclaim" and "should be stricken" for the same reasons that BDSI's counterclaim was dismissed. [D.E. 36] 21–22. As for BDSI's Sixth Affirmative Defense, Aquestive argues that it should be stricken because "to the extent there are any facts to support the defense, they are the same inadequate facts BDSI plead[ed] for its inequitable conduct counterclaim." Id. at 22.

"[D]efendants must satisfy Rule 9(b) when they plead affirmative defenses sounding in fraud." Bakery & Confectionary Union & Indus. Int'l Pension Fund v. Just Born II, Inc., 888 F.3d 696, 704–05 (4th Cir. 2018); see Andritz, 2020 WL 4495267, at *6. Under Rule 12(f), a court may strike an affirmative defense alleging inequitable conduct that is not pleaded with particularity. See Waste Mgmt., 252 F.3d at 347; Andritz, 2020 WL 4495267, at *6. Nevertheless, a motion to strike is a "drastic remedy," and where granted, courts typically provide defendants with leave to amend.

Waste Mgmt., 252 F.3d at 347 (quotation omitted); see SAS Inst. Inc. v. Akin Gump Strauss Hauer & Feld, LLP, No. 5:10-CV-101-H, 2011 WL 5417124, at *4 (E.D.N.C. June 27, 2011) (unpublished), report and recommendation adopted by 2011 WL 5439086, at *1 (E.D.N.C. Nov. 9, 2011) (unpublished).

In Aquestive's motion to strike, Aquestive relies on the same arguments it made concerning BDSI's Amended Third Counterclaim. See [D.E. 36] 21–22; [D.E. 39] 11. However, it is not clear that BDSI's affirmative defenses alleging "unenforceability" and "unclean hands" are based on the same grounds as BDSI's inequitable conduct counterclaim. See [D.E. 36] 21–22; [D.E. 38] 24; [D.E. 39] 11; see, e.g., Gilead Scis., Inc. v. Merck & Co., 888 F.3d 1231, 1239–40 (Fed. Cir. 2018); Therasense, 649 F.3d at 1287 (explaining several ways that "[i]nequitable conduct . . . diverged from the doctrine of unclean hands."). In any event, at this stage of the litigation, the court need not address that issue. At bottom, Aquestive bases its motion to strike on the same inadequate pleading arguments Aquestive made concerning BDSI's inequitable conduct counterclaim. See [D.E. 39] 11. Thus, insofar as either affirmative defense relies on BDSI's allegations concerning uniformity requirements, Aquestive's argument fails. Accordingly, the court denies Aquestive's motion to strike.

IV.

In sum, the court DISMISSES AS MOOT plaintiff's motion to dismiss defendant's Third Counterclaim and motion to strike [D.E. 29], GRANTS IN PART and DENIES IN PART plaintiff's motion to dismiss defendant's Amended Third Counterclaim [D.E. 35], and DENIES plaintiff's motion to strike defendant's Fourth and Sixth Affirmative Defenses [D.E. 35].

SO ORDERED. This 16 day of March 2021.

JAMES C. DEVER III
United States District Judge